EXHIBIT K

markush.commenis@uspto.gov

Testimony of

Harold C. Wegner

responsive to Proposed Rulemaking

EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE

72 Federal Register 44992

August 10, 2007

The Director is respectfully requested to reconsider the proposed rulemaking in light of the statutory *right* to present a generic claim. He is also respectfully requested to reconsider the denial of an appeal to any such denial as contrary to controlling precedent. Above all, the proposed rulemaking unduly complicates and frustrates biotechnology and pharmaceutical applicants from obtaining fair coverage for their pioneer innovations.

The basis for the position of undersigned is spelled out in detail in a forthcoming article, *The Eagle Right to Generic Protection,* which is incorporated herein by reference and provided as an attachment as part of this testimony.

These remarks are *pro bono* and as explained in *The Eagle Right...,* p. 1, n.*; professional affiliations are explained, *id.,* p. 1, n.**.

Respectfully submitted,

Harold C. Wegner

hwegner@gmail.com
hwegner@foley.com

THE *EAGLE* RIGHT TO GENERIC PROTECTION*

Harold C. Wegner**

I. OVERVIEW

The United States Patent and Trademark Office (PTO) has published a proposed *Generic Claim Rulemaking* that, if adopted, would fundamentally restructure the examination of generic inventions, going so far as to empower an Examiner a right to deny examination of any claim "difficult to construe".[1] The rules package would *substantively* deny patent applicants the right to generic protection for some inventions and *procedurally* proscribe a merits appeal of such denial.

This paper explores the role of the generic claim and considers how the *Generic Claim Rulemaking* fits within the statutory patent landscape. Generic patent protection provides a unique form of protection particularly for the pioneer inventor, including those in universities and startup research organizations. *See* § II, *The Role of the Generic Invention.* For the past 137 years, there has been a *right* to examination of a generic claim that reads on an elected species invention – even though the genus includes other nonelected, independent and distinct species. *See* § II-A, *The Eagle Right to Generic Protection.* The practice first arose in late nineteenth century mechanical practice. *See* § II-A-1, *The Right to a Mechanical Genus.* Contemporaneously, German dyestuff chemists introduced what is today classic Markush practice by defining a new core molecule which could have optional substituents designated by the "R" group; this practice migrated from the dyestuff laboratories on the Rhine and elsewhere to the Kaiserliches Patentamt in

---

* This paper represents the views of the author and does not necessarily reflect the views of any colleague, organization or client thereof. The author acknowledges involvement in several cases cited in this paper, either for a party or an amicus bar association, *In re Haas*, 486 F.2d 1053 (CCPA 1973)("Haas I"); *In re Weber*, 580 F.2d 455 (CCPA 1978); *In re Haas*, 580 F.2d 461 (CCPA 1978)("Haas II"); *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

**Former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School. Partner, Foley & Lardner LLP. [hwegner@foley.com]

[1]This coined abbreviation is more formally styled as *Examination of Patent Applications that Include Claims Containing Alternative Language*, 72 Federal Register 44992 (August 10, 2007)(notice of proposed rulemaking)(quoting proposed 37 CFR § 1.75(j)(1)).

Berlin; English language translations from the original German found their way to Washington, D.C., as U.S. counterpart patent applications, the true birth of the "R" group Markush practice. *See* § II-A-2, *From 19th Century German Dye Labs to the U.S. Patent Office.*

From the earliest days of generic claiming there has all too often been a difficulty grasping the concept that one *generic* invention may include several *species* embodiments which, when separately claimed, are also individual inventions. All too often, it was also thought – erroneously – that if there are, say, five species within a genus, the grant of a generic patent is *substantively* identical to five separate species patents. *See* § II-B, *Generic Protection may be the Pioneer's Sole Protection.*

While derived from generic practice in the mechanical arts, by the time of the 1952 Patent Act, generic or Markush practice was an essential integer of chemical practice with a well-defined set of rules for how to claim a generic chemical invention. *See* § II-C, *Pre-1952 Patent Act Definition of Markush Groups.* If anything, the past generation has seen a growing importance of generic protection for universities and smaller research organizations, often comprised of professors and other entrepreneurs who have migrated out of the academic community. These scientific pioneers often have *only* generic protection for commercial reward versus the *species* protection granted to multinational research organization who perfect species innovations based upon the earlier pioneer disclosures. *See* § II-D, *Pioneer Research Organizations Need Generic Protection.*

More than fifty years ago with the implementation of the 1952 Patent Act, "division" practice that had been appealable as a *substantive* matter was converted into the wholly procedural world of "restriction" practice, thanks to the statutory safeguard of 35 USC § 121. *See* § III, *35 USC § 121 under the 1952 Patent Act.* By the 1970's, however, attempts were made to twist this statutory provision to deny *single claims* because they embrace plural, patentably distinct species. It became clear that there was no statutory basis in the new law to deny a generic claim under the procedural basis of 35 USC § 121. *See* § III-A, *The Weber Restriction of § 121 to Restriction Between Claims.* Yet, attempts were then made to resurrect a case law "improper Markush" rejection from before the 1952 Patent

Act. While *dicta* has suggested the possibility for such a rejection, the test case that sought to resurrect an "improper Markush" rejection was met with a *holding* that *reversed* the PTO. *See* § III-B, *Harnisch Underscores the Correctness of Weber.* The Federal Circuit, too, has endorsed CCPA precedent excluding a statutory basis for denying a Markush claim. *See* § III-C, *The Federal Circuit Explanation in Watkinson.*

Most recently, the PTO has proposed new rules that would repudiate much of the established practice. *See* § IV, *Generic Claim Rulemaking.* The new rules would exclude the right to examine certain generic claims. *See* § IV-A, *The Proposed Rules.* In contravention of established precedent, withdrawal of claims as not meeting the proper definition of a generic invention would exclude the right to appeal. *See* § IV-B, *Right to Appeal Denial of Examination of a Genus.*

Clearly, even though there will be challenges to any proposed rulemaking as exceeding the rulemaking authority of the PTO, there clearly *is* an "anti-Markush" climate at the PTO today. Patent applicants are well advised to choose true generic terminology whenever possible and to avoid enumerative Markush expressions that actually provide *narrower* protection but *seemingly* a broader search challenge. *See* § V, *Adapting to an Anti-Markush Climate at the PTO.*

II. THE ROLE OF THE GENERIC INVENTION

A. The *Eagle* Right to Generic Protection

1. The Right to a Mechanical Genus

While it is the obligation of the Examiner to determine whether a claimed invention passes patentability muster, it is the burden of the applicant to *define* what he regards as his invention: His "specification shall conclude with… claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[2] Thus, "[a]n applicant is given, by the statute, the *right* to claim his invention with the limitations he regards as necessary to circumscribe that invention[.]"[3] The statute "allows the inventor to claim the

[2] 35 USC § 112, ¶ 2.

[3] *In re Weber*, 580 F.2d 455, 458 (CCPA 1978)(Baldwin, J.)(emphasis added).

invention as he contemplates it."[4] This requirement is not new; it may be traced back 137 years to the Patent Act of 1870 that for the first time included the obligation on the part of the inventor to provide a specification that "particularly point[s] outs and *distinctly claim*[*s*] the part, improvement, or combination which he claims as his invention or discovery."[5]

Insofar as there is an enabled disclosure of a broad invention that neither reads directly on the prior art nor on an embodiment rendered obvious by the prior art, the applicant generally will seek a *generic* claim that may, within its scope, include mutually patentably independent and distinct species. The right to claim a generic invention including independent and distinct species was established by Commissioner Fisher in 1870 in the *Eagle* case[6] – contemporaneously with the introduction of the forerunner to the second paragraph of 35 USC § 112, ¶ 2.

Mr. Eagle invented a patentable box combination invention. The patentable genus was illustrated by plural drawing figures; each was also individually claimed as a species. The plural species were independent and distinct from each other. It was clear that in the absence of an allowable genus, a "division" requirement to restrict the patent application of Mr. Eagle to one of the plural independent and distinct inventions was entirely proper under the practice of 1870. Yet, Mr. Eagle also presented a generic claim to the patentable box, *per se,* without restriction to any of the species shown in the drawing figures.

In *Eagle,* Commissioner Fisher expressly approved the presentation of a generic claim readable on an elected species: The patentee "may fairly describe several species of this genus, and may make any claim that is generic in its

---

[4] *Id.* (discussing 35 USC § 112, ¶ 2)(citing *In re Wolfrum*, 486 F.2d 588 (CCPA 1973)).

[5] D. Chisum, Chisum on Patents, § 8.02[2](2007)(quoting Act. of July 8, 1870, ch. 230, § 26, 16 Stat. 198)("The Patent Act of 1870 further formalized the requirement of claims by providing ... that the inventor 'shall particularly point out and distinctly *claim* the part, improvement, or combination which he claims as his invention or discovery.'")(original emphasis).

[6] *Ex parte* Eagle, 1870 C.D. 137 (Comm'r dec. 1870).

character and includes them all [in his generic claim]."[7] *Eagle* became ensconced as bedrock practice of the Office to the point that at the dawn of the twentieth century that *generic* protection is permitted while "[i]t [became] one of the best-settled rules of the Office that alternative forms of an invention cannot be *specifically* claimed in one application ...."[8]

2. From 19th Century German Dye Labs to the U.S. Patent Office

Markush chemical practice was born on the Continent in dyestuff laboratories where chemists used the "R" group – or some other arbitrary letter designation – to define an optional substituent on newly created aromatic dyestuff ring structures. From dyestuff laboratories on the Rhine and elsewhere patent applications were drafted and filed at the Kaiserliches Patentamt in Berlin using this same terminology, whereupon United States counterpart applications were filed using the very same "R" and related arbitrary letter designations in what were later termed to be "Markush" claims. (The "R" designation may have been shorthand for *Rest* – or "group".)

Typically, a dyestuff laboratory would create a novel complex ring structure, and then describe that structure and derivative structures comprising a family of compounds. In the basic embodiment, the ring carbon atom was unsubstituted, i.e., it possessed a bond to a hydrogen atom. Or, a substituted form could be created designated by "R". The German dyestuff chemists developed the "R" definition for ring carbon atom substituents which would be defined as hydrogen ("H") for

---

[7] *Eagle*, 1870 C.D. at 138. But, at the time, the patentee was limited to one species claim falling under the genus: " In addition to this, as the genus can only be illustrated by at least one of its species, he may select one of the embodiments of his invention for specific claims; but he cannot found one claim on one species, and a second on another, a third on another, and so on." *Id.*

[8] D. Chisum, Chisum on Patents, § 12.02[2][e] n.56 (2007)(quoting *Ex parte* Burmeister, 1902 C.D. 364 (Comm'r Pat. 1902)(emphasis added)). Also cited are *Ex parte* Butcher, 1904 C.D. 60 (Comm'r Pat. 1904); *Ex parte* Brown, 1904 C.D. 50 (Comm'r Pat. 1903); *Ex parte* Dallas, 1903 C.D. 325 (Comm'r Pat. 1903); *Ex parte* Welch, 1900 C.D. 190 (Comm'r Pat. 1900); *Ex parte* Smith, 1888 C.D. 131 (Comm'r Pat. 1888); *Ex parte* McDougall, 1880 C.D. 147 (Comm'r Pat. 1880); *Ex parte* Smith, 1879 C.D. 216 (Comm'r Pat. 1879); *Ex parte* Stown, 1873 C.D. 30 (Comm'r Pat. 1873); *Ex parte* Herreshoff, 1903 C.D. 376 (Comm'r Pat. 1903); *Ex parte* Nash, 1903 C.D. 181 (Comm'r Pat. 1903); *Ex parte* Plumley, 1902 C.D. 353 (Comm'r Pat. 1902). *Id.*

the unsubstituted form or by a variety of optional groups. Already in the nineteenth century, German dyestuff terminology was translated into English for American patent applications that resulted in early United States patents long antedating the difficulties faced much later by Mr. Markush in securing generic protection.[9]

B. Generic Protection may be the Pioneer's *Sole* Protection

At first blush, it may seem that there is no difference in substance between the grant of a single patent with a generic claim versus plural patents to various subgenera or species. But, the whole of the genus is greater than the sum of its individual parts. Generally, there is no way that the grant of splinters of a genus through restriction practice will equal the protection granted by a genus.

First, if there are subgenera or species A, B, C..., X, Y and Z within a genus, it will rarely be the case that *all* of the subgenera or species A, B, C..., X, Y and Z will be specifically disclosed or otherwise separately supported. Thus, if species "M" or "N" within the genus is not expressly named or otherwise specifically supported, then there will be no way that *any* protection will be available for "M" or "N" if the generic claim is denied. While the Examiner may very well say that M" and "N" are patentably independent and distinct from other species for purposes of safeguarding the patent applicant from a double patenting rejection under 35 USC § 121, the Examiner cannot provide missing *specific support* under 35 USC § 112, ¶ 1, for such subgenera or species. This problem is not new; it has been expressly recognized in the judicial literature:

As explained in *Weber* "[a]s a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those

---

[9] Harold C. Wegner, *The Right to Generic Chemical Coverage*, 6 AM. INTEL. PROP. L. ASS'N. Q. J. 257, 262-63 (1978)(identifying three German-origin United States patents using Markush "R"-group type of claiming). There are also early twentieth century pre-Markush examples of Markush claiming including one where "R" is defined as either a methyl or carboxylic acid group. *In re Harnisch*, 631 F.2d 716, 720 n.4 (1980)(quoting *Ex parte Markush*, 1925 CD 126 (Com.Pat.1924)(Kinnan, Ass't Comm'r))("U.S. Patent No. 901,675 [which] contained claims in which 'the letter R is used in a chemical formula as standing for CH_3 or COOH'...").

claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification."[10] The problem is exemplified by *Fields* "wherein a subgenus was not described"[11] and *Ruschig* "wherein a species of a properly described genus was found not to be described."[12]

Even if there are properly supported subgeneric or species embodiments for, say, species "C", the filing of a divisional application to a fully supported species "C" may not provide *any* coverage if a competitor has filed a patent application to the same species "C" that is *senior* to the applicant's invention of species "C", but where the applicant has plural species far senior in date to species "C". Assuming that species "C" is separately patentable, the *only* protection that the inventor will have for "C" is through his generic claim: Losing that generic claim, the inventor has no protection at all for species "C".

C. Pre-1952 Patent Act Definition of Markush Groups

The right to generic coverage under the case law up until the 1952 Patent Act followed the *Eagle* practice, permitting a generic expression to claim a family of products having a common element and a common utility, even though *portions* of the compounds may differ from each other. The case law running up until the 1952 Patent Act expressly permitted claiming a generic invention where ""the court found all of the compounds included in the claims … hav[e] a common function. The court noted [in *Jones*] that in any Markush group the compounds 'will differ from each other in certain respects.' It laid down the proposition… that

---

[10] *In re Weber*, 580 F.2d 455, 458 (CCPA 1978)(Baldwin, J.)(footnote omitted).

[11] *Weber*, 580 F.2d at 458 n. 7 (citing *Fields v. Conover*, 443 F.2d 1386 (CCPA 1971)).

[12] *Id.* (citing *In re Ruschig*, 379 F.2d 990 (CCPA 1967)).

in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components."[13]

D. Pioneer Research Organizations Need Generic Protection

Generic protection for a basic invention is fundamental for universities and small research organizations which need to obtain broad patents for their discoveries to obtain financial return for their fundamental discoveries. If all patent protection were reduced to species protection, a university or small research organization that owned basic technology patent rights would not only be forced to file numerous divisional applications, but, more importantly, they would be limited to protection for the actual species that they disclose in their patent applications – generally only a minute fraction of the literally millions of variables possible within the scope of many generic claims, particularly in the area of pharmaceutical and biotechnology research.

The pharmaceutical research regime typically operates with a university or small research organization discovering a breakthrough molecule; a patent application is filed with broad claims and a handful of working examples. Based upon publication of the disclosure in the patent application of a very basic invention, the largest pharmaceutical concerns then collectively focus the efforts of sometimes literally *thousands* of Ph.D. scientists to create literally tens of thousands of new molecules within the penumbra of the original generic patent disclosure. It is generally one or several of these new compounds that is the home run cancer cure or other life-saving therapy. The major pharmaceutical company obtains a strong *species* patent to this breakthrough medication, while taking a license from the university or small research organization under that organization's *generic* patent.

---

[13] *In re Harnisch*, 631 F.2d 716, 721-22 (CCPA 1980)(construing *In re Jones*, 162 F.2d 479 (CCPA 1947) ("[T]he court found all of the compounds included in the claims were plant growth stimulants, thus having a common function. The court noted that in any Markush group the compounds 'will differ from each other in certain respects.' It laid down the proposition, with which the PTO agrees in its MPEP, that in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components.").

If generic coverage is denied to the university or small research organization then it effectively dedicates to the public all rights to the millions of compound falling under its original genus, and receives no reward at all.

III. 35 USC § 121 UNDER THE 1952 PATENT ACT

A. The *Weber* Restriction of § 121 to Restriction Between Claims

The 1952 Patent Act introduced for the first time a statutory proscription on double patenting in the event that the Examiner made a mistake in issuing a "division" requirement – or, a "restriction" requirement under the modern wording since the 1952 Patent Act. Prior to the 1952 Patent Act, a faulty division requirement could end up with a holding of double patenting of patentably indistinct claims in a later proceeding *despite the fact that plural patents were obtained because of an Examiner's requirement for a "division"*. The statutory safeguard against double patenting following a restriction requirement was introduced into the law in 1952 precisely to eliminate a right to *appeal* a restriction requirement and to make the matter of restriction practice entirely procedural.

The statutory safeguard has absolutely nothing to do with unity of invention *within* a claim, but everything to do with restriction *between claims*.[14]

In *Weber,* the court "h[e]ld that a rejection under [35 USC §] 121 violates the basic right of the applicant to claim his invention as he chooses."[15] Clearly, § 121 has nothing to do with denial of a *single claim*.[16]

---

[14] *Weber,* 580 F.2d at 459 (Rich, J., concurring) (citing P. J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. p. 1, at p. 34 (1954))("[35 USC § 121 gave "the Commissioner a discretionary, unappealable power to *restrict* an application to one of several *claimed* inventions when those inventions were found to be 'independent and distinct.' 35 U.S.C. § 121, first sentence[.]")(original emphasis).

[15] *Weber,* 580 F.2d at 459.

[16] *Weber,* 580 F.2dd at 460 (Rich, J., concurring)(citing Federico, *supra* at p. 34; 37 CFR § 1.144)("Dealing, as it does, with requirements for restriction, [35 USC] § 121 says nothing whatever about the rejection of claims, a matter entirely separate from restriction. For one thing, rejections are appealable to the board and restriction requirements are not.")

Eagle is cited as authority for the proposition that since 1870 "at least, the expression used in [35 USC] § 121, 'two or more * * * inventions are claimed,' has connoted separate claims to separate inventions. It has no reference to generic or broad claims which 'embrace' (the term used by the examiner and the board herein) or 'cover' (the term used in the solicitor's brief in support of the board) two or more inventions. Section 121 nowhere uses the words 'embraced' or 'covered.' It says 'claimed,' and that I take to mean what it has always referred to in the terminology of the patent law, a 'claim' or definitional paragraph which, in the words of [35 USC]§ 112, second paragraph, is 'particularly pointing out and distinctly claiming the subject matter the applicant regards as his invention.'"[17]

"There is nothing [in 35 USC § 121] to excuse a refusal to examine an elected invention or an applicant's generic (broad) claim reading thereon, notwithstanding the generic claim reads on nonelected inventions and possibly many others, all potentially separately patentable. … It is elementary patent law that the number of 'species' 'covered' by a patent having a generic claim is virtually without limit notwithstanding the limitation of Rule 141 to five species 'specifically claimed.' So the discretionary power to limit one application to one invention is no excuse at all for refusing to examine a broad generic claim no matter how broad, which means no matter how many independently patentable inventions may fall within it."[18]

B. *Harnisch* Underscores the Correctness of *Weber*

The holdings of the CCPA in the wake of the 1952 Patent Act concerning attempts to deny generic Markush protection to applicants have *supported* the *Jones* view of the law that a Markush claim is proper where all of the embraced compounds have a common structural feature and share a common utility. There is nothing from the judiciary in the wake of *Weber* or *Haas II* to the contrary.

---

[17] *Weber*, 580 F.2d at 459-60 (Rich, J., concurring)(citing *Ex parte Eagle*, 1870 C.D. 137 (Com'r. Pats.1870).

[18] *Weber*, 580 F.2d at 460-61 (Rich, J., concurring).

Indeed, *Harnisch* – a case often cited for the contrary proposition by the PTO – has a *holding* that the contested Markush group *is* proper under the pre-1952 case law.

Insofar as any PTO argument is made keyed to *Harnisch* that *Weber* and *Haas II* may be incorrect in their interpretation of 35 USC § 121, such an argument flies directly in the face of the statement found in *Harnisch* itself that "[i]t should … be clear … that we adhere to our holdings in *In re Weber*[, 580 F.2d 455 (CCPA 1978)]. and *In re Haas* (Haas II)[, 580 F.2d 461 (CCPA 1978)]. Nothing we have said [in *Harnisch*] is intended to change or modify them in any way; nor do we think anything said could be reasonably construed to have such an effect."[19]

C. The Federal Circuit Explanation in *Watkinson*

As explained by the Federal Circuit in the *Watkinson* case: "Under ... *Weber*... and [*Haas II*], it is *never* proper for an examiner to reject a Markush claim under 35 U.S.C. § 121. Section 121 simply does not authorize such a rejection."[20]

IV. GENERIC CLAIM RULEMAKING

A. The Proposed Rules

The *Generic Claim Rulemaking* package prescribes the form of generic claims that are permitted and, absent meeting the rules, the claims would be *withdrawn* from consideration *without a right of appeal to the Board (or the court)*. Thus, proposed Rule 140[21] rewrites restriction practice by saying that a

---

[19] *Harnisch*, 631 F.2d at 722.

[20] *In re Watkinson*, 900 F.2d 230 (Fed. Cir. 1990) (Baldwin, J.)(original emphasis) (citing *Weber, Haas II*).

[21] "[Proposed 37 CFR]§ 1.140. Requirement for a claim to be limited to a single invention in an application filed under 35 U.S.C. 111(a).
"(a) Two or more independent and distinct inventions may not be claimed in a single claim. See § 1.75(a). A claim that reads on multiple species using alternative language is limited to a single invention when all the species encompassed by the claim meet at least one of the following two conditions:
"(1) The species share a substantial feature essential for a common utility, or
"(2) The species are prima facie obvious over each other.

single claim may cover plural inventions, instead of one generic invention as in *Eagle* and 137 years of progeny. Thus, it is stated that "[a] claim that reads on multiple species using alternative language is limited to a single invention when all the species encompassed by the claim …share a substantial feature essential for a common utility[.]".[22]

(To be sure, the applicant can alternatively admit unpatentability of all members of the genus if any one is found unpatentable;[23] such an admission would be foolish and contrary to the established principle that the equivalency of the Markush members is part of *the applicant's* discovery.[24])

Proposed Rule 142(b) permits restriction between inventions *within a claim*: "The propriety of a requirement for restriction shall be determined without regard to whether the plural inventions are recited in separate claims or as alternatives within a single claim."[25] Proposed Rule 75(j) would provide strict formal

---

"(b) The presentation of a claim that reads on multiple species using alternative language (§ 1.75(j)) may be accompanied by a statement explaining why the claim is limited to a single invention. Such a statement shall be considered by the Office if filed by the applicant at the same time as the presentation of such a claim and may be considered by the Office if filed by the applicant after the presentation of such a claim but before the mailing date of any restriction requirement or action on the merits."

[22] Proposed Rule 140(a)(1).

[23] Thus, under proposed Rule 140(a)(2) there is one single invention if "[t]he species are prima facie obvious over each other."

[24] *In re Dillon,* 919 F.2d 688, 694 (Fed. Cir. 1990)(en banc)(Lourie, J.)("caution[ing] against [the] practice [of using an applicant's own showing of equivalence against her in violation of the rule of *In re Ruff,* 256 F.2d 590, 596 (CCPA 1958)]"); *see also In re Lam,* 35 Fed.Appx. 889, 897-98 (Fed. Cir. 2002)(" In *In re Ruff,* our predecessor court reversed an obviousness rejection based on an applicant's own disclosure that two classes of organic compounds (amino and mercapto compounds) were both effective tarnish inhibitors. 256 F.2d at 595. Though the amino compounds were known in the art, the applicant himself invented and taught the use of the mercapto compounds. *Id.* The Board in the *Ruff* case mistakenly interpreted several earlier cases to hold that such a disclosure by an applicant could support a finding of equivalency. The court disabused the Board of that notion and squarely held that the applicant's own teaching of the tarnish-fighting mercapto compounds, the utility of which he himself discovered, could not be used to show equivalence even though the applicant also disclosed that the prior art amino compounds performed a similar function. [256 F.2d] at 597.").

[25] Proposed 37 CFR § 1.142(b).

guidance on how a generic claim could be drafted; failure to meet the strict guidance would result in an *objection* and presumably a petitionable but not appealable matter.[26]

The arbitrary nature of the *Generic Claim Rulemaking* package is manifested by the right of the Examiner to deny consideration of a claim where "[t]he number and presentation of alternatives in the claim ...make[s] the claim difficult to construe[.]"[27]

Clearly, there is nothing in 35 USC § 121 that has anything to do with restriction *within* a claim. If the PTO considers a claim to be an "improper" Markush or other type of generic claim, then a statutory basis should be found for such a rejection. There clearly is no *holding* in *Harnisch* that in any way supports a *rejection* of a Markush or other claim: The *holding* in *Harnisch* was, to the contrary, a determination that the claimed invention *was* proper: The rejection in *Harnisch* was *reversed.*

B. Right to Appeal Denial of Examination of a Genus

The *Generic Claim Rulemaking* would take away the right of an *appeal* for a violation of the PTO's new rules on generic claiming. But, the right to *appeal* a restriction requirement or other "procedural" withdrawal of a generic claim was established in *Haas I.*[28]

---

[26] Proposed 37 CFR 1.75(j) "A claim that reads on multiple species by using alternative language must meet the following conditions:
"(1) The number and presentation of alternatives in the claim does not make the claim difficult to construe;
"(2) No alternative is defined as a set of further alternatives within the claim; and
"(3) No alternative is encompassed by any other alternative within a list of alternatives, unless there is no other practical way to define the invention.
"(4) Each alternative within a list of alternatives must be substitutable one for another."

[27] Proposed 37 CFR § 1.75(j)(1).

[28] *In re Haas*, 486 F.2d 1053, 1055 (CCPA 1973)("Haas I").

As explained in *Digital Equipment,* "in determining whether a particular PTO action is appealable to the Board (and hence reviewable either by the Court of Customs and Patent Appeals or by the district court in a civil action instituted pursuant to [35 USC §] 145), one must 'look both to the language employed (by the agency in taking the action) and the effect thereof,' and consider 'both form and substance.'"[29] Thus, "[i]n *Haas,* the court held that the Board had jurisdiction to review an examiner's 'withdrawal' of claims, which 'amount[ed] to a rejection' because it precluded further consideration of the claims 'not only in this application but prospectively in any subsequent application because of their content.'"[30]

The label of a "rejection" clearly is not necessary for an appeal: "[T]he PTO's failure to label its present action in terms of "rejection" may have little practical significance other than to purportedly insulate from the [appellate] review mechanism mandated by Congress a decision that is highly factual and substantive in nature, and thus particularly appropriate for such review."[31]

V. ADAPTING TO AN ANTI-MARKUSH CLIMATE AT THE PTO

Although it is unlikely that any anti-Markush rulemaking that may be issued in *final* form would become effective until some point well into 2008, it is important as a matter of daily practice to adapt to the realities of everyday patent practice that Examiners do not like lengthy, multi-page Markush claims.

There is much that can be done *without* compromising the applicant's substantive right of protection for his genus:

---

[29] *Digital Equipment Corp. v. Diamond*, 653 F.2d 701, 713 (1st Cir. 1981)(quoting *Haas I*, 486 F.2d at 1055).

[30] *Id.*, quoting *Haas I*, 486 F.2d at 1056.

[31] *Digital Equipment*, 653 F.2d at 713.

A. Generic Expressions without Markush Symbols

Markush practice has been used far too often as a shortcut to avoid devising a true generic expression that may provide broader coverage and avoid the complexities of Markush practice. Even if there is no art-recognized generic term nor a generic term which clearly defines precisely the genus the applicant has in mind in drafting the application, nevertheless the applicant is free to be his own lexicographer and provide a specific definition for a generic term that will control its meaning both before the PTO and in enforcement proceedings.[32]

B. Enumerative Markush Definitions Should be Avoided

Consider the situation where a novel and unobvious core compound may be optionally substituted by phenyl or any substituted phenyl group.

Applicants unduly complicate their prosecution when they attempt to enumerate every possible substituent on an aromatic ring. For example, if an "R" group is defined as being "a substituted phenyl group" this can be written quite simply in the claim, making it easy to understand and examine.

But, if there is an *enumeration* of the possible substituents in the claim, the definition for what "substituted phenyl" may run over a page or two which – together with other variables similarly defined – can lead to a "claim 1" running ten or more pages, to the frustration of everyone. "Substituted phenyl" represents a relatively easy challenge, yet an attempt to enumerate all the variables in the specification can produce a definition several pages long.[33] Yet, when one has an

---

[32] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)(*en banc*)(Bryson, J.)("[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs.")(citation omitted) .

[33] For example, for exemplification of "substituted phenyl", *see* Rawson *et al.*, U.S. 7,250,447 (2007) ("'[S]ubstituted phenyl' is a phenyl group substituted with one, two, three, four or five substituents chosen from halogen (F, Cl, Br, I), hydroxy, protected hydroxy, cyano, nitro, alkyl (e.g. C1-C6 alkyl), alkoxy (e.g. C1-C6 alkoxy), benzyloxy, carboxy, protected carboxy, carboxymethyl, protected carboxymethyl, hydroxymethyl, protected hydroxymethyl, aminomethyl, protected aminomethyl, trifluoromethyl, alkylsulfonylamino, arylsulfonylamino, heterocyclylsulfonylamino, heterocyclic, aryl, or other groups specified. Examples of the term 'substituted phenyl' includes but is not limited

enumerative Markush definition *in the claim* it is likely that *some* possible variable will be omitted, which manifests the fact that a ten-plus page enumerative Markush claim may provide coverage far narrower than a simple, one paragraph claim that recites "R" as being "substituted phenyl".

C. A Common Utility Statement for All Members

Particularly where a generic definition of products is provided for a claim, it is important to repeat that *same definition* in the specification, followed by a statement of the common utility shared by all of the products within that definition: Where *all* the compounds share a common utility and have a common structural

---

to a mono- or di(halo)phenyl group such as 4-chlorophenyl, 2,6-dichlorophenyl, 2,5-dichlorophenyl, 3,4-dichlorophenyl, 3-chlorophenyl, 3-bromophenyl, 4-bromophenyl, 3,4-dibromophenyl, 3-chloro-4-fluorophenyl, 2-fluorophenyl and the like; a mono- or di(hydroxy)phenyl group such as 4-hydroxyphenyl, 3-hydroxyphenyl, 2,4-dihydroxyphenyl, the protected-hydroxy derivatives thereof and the like; a nitrophenyl group such as 3- or 4-nitrophenyl; a cyanophenyl group, for example, 4-cyanophenyl; a mono- or di(C1-C6 alkyl)phenyl group such as 4-methylphenyl, 2,4-dimethylphenyl, 2-methylphenyl, 4-(iso-propyl)phenyl, 4-ethylphenyl, 3-(n-propyl)phenyl and the like; a mono or di(alkoxy)phenyl group, for example, 3,4-dimethoxyphenyl, 3,4-diethoxyphenyl, 3-ethoxy-4-isopropoxyphenyl, 3-ethoxy-s-butoxyphenyl, 3-methoxy-4-benzyloxyphenyl, 3-methoxy-4-(1-chloromethyl)benzyloxy-phenyl, 3-ethoxyphenyl, 4-(isopropoxy)phenyl, 4-(t-butoxy)phenyl, 3-ethoxy-4-methoxyphenyl and the like; 3- or 4-trifluoromethylphenyl; a mono- or dicarboxyphenyl or (protected carboxy)phenyl group such 4-carboxyphenyl; a mono- or di(hydroxymethyl)phenyl or (protected hydroxymethyl)phenyl such as 3-(protected hydroxymethyl)phenyl or 3,4-di(hydroxymethyl)phenyl; a mono- or di(aminomethyl)phenyl or (protected aminomethyl)phenyl such as 2-(aminomethyl)phenyl or 2,4-(protected aminomethyl)phenyl; or a mono- or di(N-(methylsulfonylamino))phenyl such as 3-(N-methylsulfonylamino))phenyl. Also, the term 'substituted phenyl' represents disubstituted phenyl groups where the substituents are different, for example, 3-methyl-4-hydroxyphenyl, 3-chloro-4-hydroxyphenyl, 2-methoxy-4-bromophenyl, 4-ethyl-2-hydroxyphenyl, 3-hydroxy-4-nitrophenyl, 2-hydroxy-4-chlorophenyl, and the like, as well as trisubstituted phenyl groups where 1, 2, or 3 of the substituents are different, for example 3-methoxy-4-benzyloxy-6-methyl sulfonylamino, 3-methoxy-4-benzyloxy-6-phenyl sulfonylamino, and tetrasubstituted phenyl groups where the substituents are different such as 3-methoxy-4-benzyloxy-5-methyl-6-phenyl sulfonylamino. Exemplary substituted phenyl groups include the 3-methoxyphenyl, 3-ethoxy-phenyl, 4-benzyloxyphenyl, 4-methoxyphenyl, 3-ethoxy-4-benzyloxyphenyl, 3,4-diethoxyphenyl, 3-methoxy-4-benzyloxyphenyl, 3-methoxy-4-(1-chloromethyl)benzyloxy-phenyl, 3-methoxy-4-(1-chloromethyl)benzyloxy-6-methyl sulfonyl aminophenyl groups.").

feature that establishes patentability for the class of compounds, this is the epitome of a *proper* Markush group. An enlarged panel of the PTO Board interpreted *Harnisch* in *Hozumi,* which explains the importance of the recitation of a common utility:

"The judicially created rejection of claims for 'improper Markush grouping' has most recently been discussed … in the case of *In re Harnisch*, 631 F.2d 716 (CCPA 1980).... The opinion in that case fairly thoroughly reviewed the history of this type of rejection and set forth, at least implicitly, some guidelines for determining whether or not a Markush group is proper. Broadly, the determinative factor was held to be whether there existed 'unity of invention' or whether the claims were drawn to a collection of 'unrelated inventions.' Specifically, the claims in that case were drawn to a class of compounds *all of which were both disclosed and claimed* as being 'useful as dyestuffs.' *All of them* were also *both disclosed and claimed* as being 'coumarin compounds.' Thus, *all of the claims had in common a functional utility* related to a substantial, structural feature disclosed as being essential to that utility."[34]

The PTO *Manual of Patent Examining Procedure* acknowledges that in the case of a Markush claim, "unity of invention exists where compounds included within a Markush group (1) share *a common utility*, and (2) *share a substantial structural feature* essential to that utility.".[35] This follows from the *Jones* case as

---

[34] *Ex parte Hozumi,* 1984 WL 62977, 3 U.S.P.Q.2d 1059 (PTO Bd. App. & Int. 1984)(Serota, Katz, Goldestein, Lovell, Steiner, EICS)(Goldstein, EIC)(emphasis supplied).

[35] MPEP § 803.02, *Markush Claims* [8th ed., Rev. 5 (August 2006)](" Since the decisions in *In re Weber*, 580 F.2d 455 (CCPA 1978) and *In re Haas*, 580 F.2d 461 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.").

adopted in *Harnisch* that approved a Markush group where all members are disclosed as "having a common function."[36]

VI. CONCLUSION

Applicants *should* shift more to true generic claiming, if only to avoid the anti-Markush prejudice that exists at the PTO today. Despite the shift that applicants *should* be making toward classic generic claims, situations will remain where Markush generic claiming represents a sound choice for patent applicants.

There is no magic, formulaic way to short-circuit examination of pioneer inventions in Markush – or other – format. There should be no magic cookie-cutter amount of time to examine an invention. Either the amount of time will balance out amongst the difficult pioneer cases and the multitude of routine improvement inventions, or, if not, administrative allowances must be made for the more difficult to examine cases. But, when an Einstein or other genius inventor comes forward with a pioneer invention, the PTO should applaud the innovation and grant claims commensurate in scope with the pioneer nature of the technology and not attempt to limit the scope of protection.

[36] *Harnisch*, 631 F.2d at 721-22 (construing *Jones*, 162 F.2d 479).